

**Clinical Trials Management Systems Workspace**  
**Face-to-Face Meeting**  
**Oregon Health & Science University**  
**SESSION: caAERS Functional Deep Dive**

<b>Session Information</b>	<b>Date: May 31, 2007</b> <b>Time: 9:45 a.m.–11:15 a.m. PDT</b> <b>Presenter/Lead: Edmond Mulaire and Ram Chilukuri (SemanticBits)</b> <b>Facilitator: Niket Parikh</b> <b>Scribe: Daniela Smith</b>
<b>Executive Summary</b>	<p>Project Manager Edmond Mulaire (SemanticBits) and Lead Architect Ram Chilukuri (SemanticBits) of the cancer Adverse Events Reporting System (caAERS) Team presented an overview of the application and a demonstration of its functionality. Participants agreed that caAERS should work with other groups such as cooperative groups, Medical Dictionary for Regulatory Activities (MedDRA), and Adverse Event Expedited Reporting System (AdEERS) to assess their needs and input. The caAERS Team continues to work on user interface and external system access issues/features.</p>
<b>Discussion</b>	<p><b>Discussion/Parking Lot Issues</b></p> <ul style="list-style-type: none"> <li>• The caAERS project should work with the appropriate working groups (i.e., cooperative groups) to assess their needs.</li> <li>• The caAERS application is intended to be a way for researchers to document adverse events—an adverse event data capture tool, as differentiated from a data reporting tool.</li> <li>• caAERS is not a point of care tool. There is a mechanism by which data from paper Case Report Forms (CRF) is entered as routine adverse event data. There are also mechanisms to add unanticipated and solicited adverse events.</li> <li>• A long-term goal of caAERS is to provide functional access to Cancer Central Clinical Database (C3D) or other Clinical Trial Management Systems (CTMS). Participants felt strongly that there could not be two sources of truth for information. Participants agreed that the source of truth for studies and subjects would be C3D/CTMS, and for adverse events would be caAERS.</li> <li>• An adoption activity might involve determining the source of truth through multiple methodologies.</li> <li>• Participants discussed the value of mapping of caAERS with new versions of MedDRA.             <ul style="list-style-type: none"> <li>– Cancer Therapy Evaluation Program (CTEP) updates its mapping to MedDRA annually in July (currently support MedDRA 9.0 and 9.1). MedDRA 10 will be released in July 2007.</li> <li>– Legacy data is mapped and represented in the latest MedDRA version.</li> <li>– The caAERS Team should work with the MedDRA team.</li> </ul> </li> <li>• Interaction is needed between caAERS and AdEERS. Is interaction between these systems among different institutions feasible? The goal of the caAERS Team is that an expedited report in caAERS will be able to interact with AdEERS through back-end development. Overloading of the AdEERS system can be avoided through the managed flow of data. The caAERS Team and CTEP (Ann Setser) would like to see the AdEERS front end fall away and caAERS to assume the main</li> </ul>

	<p>user interface role. The AdEERS interface would still be available for institutions not adopting caAERS.</p> <ul style="list-style-type: none"><li>• caAERS will alert reported start dates to sponsors.</li><li>• An amendment feature is needed to review data that has changed during a particular course.</li><li>• A change in the trial will alter treatment outcomes over the course of a trial, which should be captured in caAERS (i.e., attention to concomitant medications).</li><li>• The caAERS Team is working to evaluate which data elements and fields are mandatory within the user interface.</li><li>• Can caAERS data be accessed from other systems such as Patient Study Calendar (PSC)? It is conceivable that it is possible to retrieve such data from other systems.</li><li>• caAERS supports protocol-specific terminology. Richer terminology is not necessarily a part of Common Terminology Criteria for Adverse Events (CTCAE) or other systems (i.e., in-house grading/terminology).</li></ul>												
Requirements	<table><tr><th>Req. #</th><th>Name</th><th>Description</th></tr><tr><td>caAERS – R1</td><td>Working Group Input</td><td>Need to ensure appropriate working group input (i.e., cooperative groups) to caAERS. The team can work with Mayo and the coordinating center at Eastern Cooperative Oncology Group (ECOG); Kim Johnson (Cancer and Leukemia Group B) volunteered to give input.</td></tr><tr><td>caAERS – R2</td><td>caAERS and MedDRA/AdEERS Collaboration</td><td>The caAERS Team should collaborate with the MedDRA and AdEERS teams.</td></tr><tr><td>caAERS – R3</td><td>Amendment Feature</td><td>An amendment feature is needed to review data that has changed during a particular course.</td></tr></table>	Req. #	Name	Description	caAERS – R1	Working Group Input	Need to ensure appropriate working group input (i.e., cooperative groups) to caAERS. The team can work with Mayo and the coordinating center at Eastern Cooperative Oncology Group (ECOG); Kim Johnson (Cancer and Leukemia Group B) volunteered to give input.	caAERS – R2	caAERS and MedDRA/AdEERS Collaboration	The caAERS Team should collaborate with the MedDRA and AdEERS teams.	caAERS – R3	Amendment Feature	An amendment feature is needed to review data that has changed during a particular course.
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Action Items	No action items were identified for this session.												

## Attendance

#	First Name	Last Name	Affiliation
1.	Robert	Annechiarico	Duke University
2.	Elaine	Brock	Univ. of Michigan
3.	Troy	Budd	NCI/DCP
4.	Cal	Collins	Akaza
5.	Lara	Fournier	OHSU
6.	Amy	Funkhouser	ECOG
7.	Sonja	Hamilton	Mayo Clinic
8.	Virginia	Hetrick	Patient Advocate
9.	Andrea	Hwang	UC Irvine
10.	Kim	Johnson	CALGB
11.	Christie	Kaefer	NCI
12.	Warren	Kibbe	Northwestern University
13.	Jieping	Li	Georgetown
14.	Brenda	Maeske	SAIC
15.	Randy	Millikan	MD Anderson
16.	Sorena	Nadaf	Vanderbilt University
17.	Susan	Pannoni	City of Hope
18.	Niket	Parikh	Booz Allen Hamilton
19.	Kerri	Phillips	PercipEnz
20.	Gopi	Potnuru	PercipEnz
21.	Linda	Schmandt	Univ. of Pittsburgh
22.	Ann	Setser	CTEP/NCI
23.	Angela	Smith	SWOG
24.	Daniela	Smith	Booz Allen Hamilton
25.	Umit	Topaloglu	UAMS
26.	Troy	Walls	Univ. of Arkansas for Medical Sciences
27.	Sean	Whitaker	Northwestern University
28.	Julie	Zhu	Northwestern University